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April 5, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0826

Dear Sir/Madam:

On January 21, 1999 (64 Federal Register 3250-3255), the FDA published a notice of proposed rulemaking to establish new regulations, to appear at 21 C.F.R. § 101.90, to govern notifications to FDA of health claims based on authoritative statements. The notice invites the submission of written comments by April 6, 1999.

In its Federal Register document, FDA states that it is proposing to permit the use in labeling for dietary supplements of health claims based on authoritative statements under the notification procedures of the Food and Drug Administration Modernization Act of 1997 (FDAMA). FDA states that FDAMA permits nutrient content claims based on authoritative statements for both conventional foods and dietary supplements, and that FDAMA also permits health claims based on authoritative statements for conventional foods; however, FDA states that "FDAMA ... does not provide for health claims for dietary supplements based on authoritative statements." 64 Federal Register at 3251.

FDA states that it believes that conventional foods and dietary supplements should be subject to the same standards and procedures for the use of health claims, including the notification procedures established by FDAMA. Therefore, FDA states that it is proposing to issue new regulations, to be codified at 21 C.F.R. § 101.90, to provide for the use of health claims on dietary supplements based on authoritative statements.

FDA states that it intends the proposed regulations "to provide for the same process and standard for the use on dietary supplements of health claims based on authoritative statements as provided by section 403(r)(3)(C) of the [Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. § 343(r)(3)(C)] for conventional foods." 64 Federal Register at 3251.

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The Monsanto Company, a research-based life sciences company that seeks to harness the best available science to meet human needs in agriculture, nutrition and health, hereby submits the following comments in response to FDA's invitation.

FDA states that it "believes that, for health claims, conventional foods and dietary supplements should be subject to the same standards and procedures, including the notification procedure provided by FDAMA." 64 Fed. Reg. at 3251. The Monsanto Company is in complete agreement with this FDA policy. Indeed, we strongly encourage FDA to adhere to this policy of uniform treatment for dietary supplements and conventional foods, insofar as the law permits, not only for health claims but also for claims to affect the structure or function of the human body, and for other labeling claims generally. In general, insofar as a claim about a vitamin, mineral, other nutrient or other dietary ingredient is appropriate when the substance is present in a conventional food, the claim should also be appropriate when the same substance appears in a dietary supplement, and vice versa (i.e., if the claim is appropriate for a dietary supplement, it should also be appropriate for a conventional food). Likewise, insofar as FDA determines that a claim about a vitamin, mineral, other nutrient, or other dietary ingredient is not appropriate for a conventional food, we believe that, insofar as the law enables the agency to do so, it should take the position that the same claim is not appropriate in labeling for a dietary supplement that contains the substance, and vice versa (i.e., if the claim is not appropriate for a dietary supplement, it should not be appropriate for a conventional food).

However, we are not convinced by FDA's conclusion that this rulemaking is necessary to accomplish the agency's desired goal of uniform treatment for dietary supplements and conventional foods with respect to the use of authoritative statements. We recognize that the FDC Act, as amended by the Nutrition Labeling and Education Act of 1990 (NLEA), provides for procedures and standards for health claims for "food" in § 403(r)(3) (of the FDC Act), 21 U.S.C. § 343(r)(3), and then in § 403(r)(5)(D) (of the FDC Act), 21 U.S.C. § 343(r)(5)(D), provides that a health claim made with respect to a dietary supplement shall not be subject to § 403(r)(3) but instead "shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation...." However, we believe these provisions should be considered together with a more recent amendment of the FDC Act, established by the Dietary Supplement Health and Education Act of 1994 (DSHEA), i.e., the final sentence of § 201(ff) of the FDC Act, 21 U.S.C. § 321(ff), which provides that, "Except for purposes of section 201(g) [of the FDC Act, 21 U.S.C. § 321(g)], a dietary supplement shall be deemed to be a food within the meaning of [the FDC Act]."[1] We believe this 1994 amendment of the FDC Act establishes a new policy that, once it has been determined that a dietary supplement product is not a drug, the product should be regulated as a "food" and should not be regulated more restrictively than other "food" products.

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[1] The reference to "section 201(g)" in this provision is a reference to § 201(g) of the FDC Act, 21 U.S.C. § 321(g), i.e., to the definition of "drug" in the FDC Act.

We also encourage FDA to announce that, pending completion of this rulemaking, the agency invites dietary supplement companies to proceed with the use of health claims based on authoritative statements by following the procedures set forth in the proposed regulations. FDA has occasionally welcomed compliance with proposed rulemaking as an acceptable means of satisfying legal requirements. For example, the agency has invited companies to submit notifications to the agency concerning self-affirmations of GRAS status pursuant to the agency's pending proposed rulemaking on that subject, 62 Fed. Reg. 18938-18964 (April 17, 1997). We believe that, pending completion of the rulemaking concerning authoritative statements, FDA should follow the same practice and invite industry compliance with the agency's proposed regulations, and accept such compliance as sufficient to satisfy the requirements of law (or, as qualifying for discretionary non-enforcement by FDA, if the agency prefers to adhere to an interpretation that this rulemaking is necessary), pending completion of the rulemaking proceeding.

FDA has proposed that the final regulations to be issued in this rulemaking should become effective upon publication in the Federal Register and not be subject to a delayed effective date. 64 Fed. Reg. at 3253. The Monsanto Company is in complete agreement that the proposed regulations should become effective as soon as possible, and accordingly, that final regulations consistent with the proposal should become effective on the date of their publication in the Federal Register.

We hope these comments are helpful.

Respectfully submitted,

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